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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,475	07/07/2003	Stephen H. Herrmann	22058-590DIV CON	5152

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,475	HERRMANN ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/23/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 57-73 in the reply filed on 06/05/2006 is acknowledged. Applicants traverse is that the need for restriction as between any invention corresponding to SEQ ID NO:1 and SEQ ID NO:3 is now moot because new claim 74 and amended claim 67, from the remaining claims in the application depend, specifies a sequence – amino acids 22-328 or SEQ ID NO:1 – that is common to the amino acid sequences of both SEQ ID NO:1 and SEQ ID NO:3. The applicant's arguments are found persuasive and hence the restriction/election between Groups I and II as set forth in the previous office action is withdrawn.

2. Thus, claims 57-73 and the newly added claim 74 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 65 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for reciting "consists essentially of", because the exact meaning of the phrase is not clear. What does "consists essentially of mean?

Does it mean that the polypeptide consists of "SEQ ID NO:1 from amino acid 20 to amino acid 326 " or "an amino acid sequence comprising any number of amino acids from amino acid 20 to amino acid 326 of SEQ ID NO:1"? For the purposes of this office action the claims are interpreted as "...the chemokines polypeptide consists of SEQ ID NO:1 from amino acid...".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 57-74 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,730,296 (US '296). Although the conflicting claims are not identical, they are not patentably distinct from each other because Please see below.

The instant claims are summarized as drawn to a composition comprising a chimeric polypeptide, the chimeric polypeptide comprising at least one chemokine polypeptide covalently attached to at least one heterologous polypeptide is an Fc polypeptide, wherein the chemokines polypeptide comprises SEQ ID NO:1 from amino acid 22 to amino acid 328, SEQ ID NO:1, SEQ ID NO:1 from amino acid 20 to amino acid 328, SEQ ID NO:1 from amino acid 21 to amino acid 328 and SEQ ID NO:3, further comprising a pharmaceutically acceptable carrier. The claims are further drawn to a polypeptide produced according to a process comprising: (a) growing a culture of a host cell in a suitable culture medium, wherein the host cell has been transformed with a polynucleotide comprising at least one expression control sequence, wherein the polynucleotide encodes a chimeric polypeptide, the chimeric polypeptide comprising at least one chemokine polypeptide covalently attached to at least one heterologous polypeptide, wherein the chemokine polypeptide comprises of the above-mentioned polypeptides (underlined).

Claims 1-17 of US '296 are drawn to a polypeptide produced according to a process comprising: (a) growing a culture of a host cell in a suitable culture medium, wherein the host cell has been transformed with a polynucleotide comprising at least one expression control sequence, wherein the polynucleotide encodes a chimeric polypeptide, the chimeric polypeptide comprising at least one chemokine polypeptide covalently attached to at least one heterologous polypeptide, wherein the chemokine

polypeptide comprises an amino acid sequence selected from the group consisting of: (aa) SEQ ID NO:1; (ab) SEQ ID NO:1 from amino acid 20 to amino acid 328; (ac) SEQ ID NO:1 from amino acid 21 to amino acid 328; (ad) SEQ ID NO:1 from amino acid 22 to amino acid 328; (ae) SEQ ID NO:3; and (af) SEQ ID NO:3 from amino acid 20 to amino acid 326, and (b) purifying said polypeptide from the culture. Further, claims 1-17 of U.S. Patent No. 6,730,296 recite a composition comprising a chimeric polypeptide, the chimeric polypeptide comprising at least one chemokine polypeptide covalently attached to at least one heterologous polypeptide, wherein the chemokine polypeptide comprises an amino acid sequence selected from the group consisting of: (a) SEQ ID NO:1; (b) SEQ ID NO:1 from amino acid 20 to amino acid 328; (c) SEQ ID NO:1 from amino acid 21 to amino acid 328; (d) SEQ ID NO:1 from amino acid 22 to amino acid 328; (e) SEQ ID NO:3; and (f) SEQ ID NO:3 from amino acid 20 to amino acid 326.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced the composition comprising a chimeric polypeptide and a polypeptide produced according to a process comprising the method as described in claim 67 based on the teachings of claims 1-17 of US '296.

One of ordinary skill in the art would have been motivated and would have reasonable expectation of success to have used produced the chimeric polypeptide comprising at least one chemokines polypeptide covalently linked to at least one heterologous polypeptide as taught by claims 2-7 and 14-17 of US '296, wherein claims

2-7 and 14-17 of US '296 teach A composition comprising a chimeric polypeptide, the chimeric polypeptide comprising at least one chemokine polypeptide covalently attached to at least one heterologous polypeptide.

In addition, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to have used the teachings of claims 2-7 and 14-17 of US '296 to produce the composition of the instant claims because claims 2-7 and 14-17 of US '296 teach a composition comprising a chimeric polypeptide, the chimeric polypeptide comprising at least one chemokine polypeptide covalently attached to at least one heterologous polypeptide, wherein the chemokine polypeptide comprises an amino acid sequence selected from the group consisting of: (a) SEQ ID NO:1; (b) SEQ ID NO:1 from amino acid 20 to amino acid 328; (c) SEQ ID NO:1 from amino acid 21 to amino acid 328; (d) SEQ ID NO:1 from amino acid 22 to amino acid 328; (e) SEQ ID NO:3; and (f) SEQ ID NO:3 from amino acid 20 to amino acid 326.

Moreover, one of ordinary skill in the art would have known to use the teachings of claims 1 and 8-13, because claims 1 and 8-13 are drawn to A polypeptide produced according to a process comprising: (a) growing a culture of a host cell in a suitable culture medium, wherein the host cell has been transformed with a polynucleotide comprising at least one expression control sequence, wherein the polynucleotide encodes a chimeric polypeptide, the chimeric polypeptide comprising at least one chemokine polypeptide covalently attached to at least one heterologous polypeptide, wherein the chemokine polypeptide comprises an amino acid sequence selected from the group consisting of: (aa) SEQ ID NO:1; (ab) SEQ ID NO:1 from amino acid 20 to

amino acid 328; (ac) SEQ ID NO:1 from amino acid 21 to amino acid 328; (ad) SEQ ID NO:1 from amino acid 22 to amino acid 328; (ae) SEQ ID NO:3; and (af) SEQ ID NO:3 from amino acid 20 to amino acid 326, and (b) purifying said polypeptide from the culture.

Furthermore, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to have used the teachings of claims 1-17 of US '296 to produce the claimed invention because claims 1-17 of US '296 a composition comprising a chimeric polypeptide, the chimeric polypeptide comprising at least one chemokine polypeptide covalently attached to at least one heterologous polypeptide and a method of preparing such polypeptide wherein the heterologous polypeptide is an Fc polypeptide, because US '296 defines the heterologous polypeptide as Fc polypeptide (please see brief description of the invention, in particular).

> "The exceptions to the general prohibition of using the disclosure of a potentially conflicting patent or application are (i) dictionary for claim terminology and (ii) portions of the disclosure which provide support for the claims in the potentially conflicting patent or application."

Thus, the disclosure of US '296 satisfies both of the above requirements to qualify as reading on the claimed invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

6. No claims are allowed

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER